K050701

BIONIX®

510(k) Summary:

- Thigh Bolster and Foot Positioner
- SuProne Plus

1. Thigh and Foot Positioner

Date Prepared:	January 11, 2005
Submitter:	Bionix Development Corporation 5154 Enterprise Blvd. Toledo, Ohio 43612 419.727.8421 (phone) 419.727.4430 (fax)
Contact Person:	James Huttner M.D., Ph.D. [jhuttner@bionix.com (email)]
Trade Name:	Thigh Bolster and Foot Positioner Patient Positioning System
Common Name:	Thigh and Foot Patient Immobilization System
Classification Name:	Powered radiation therapy patient support assembly, accessory (per CFR section 892.5770)
Intended Use:	The Thigh Bolster and Foot Positioner from Bionix Development Corporation is designed to be used for the positioning and re-positioning of patients for receiving radiation therapy.

Claim of Substantial Equivalence:

This product is similar in design and function to existing patient positioning devices currently in use as accessories to radiation therapy systems.

Two such devices are the Dual Leg Positioner and Knee-and-Foot Lok, manufactured and legally marketed by Med-Tec, Inc. of Orange City, Iowa. These products are listed under regulation number 892.1980, and are exempt from pre-market notification.

The Dual Leg Positioner from Med-Tec is designed to immobilize the lower legs during supine hip and pelvic radiation therapy procedures. The Dual Leg Positioner consists of a one-piece vinyl-covered foam support device with a wedge-like design. The Knee-and-Foot Lok consists of two pieces of vinyl-covered foam supports; the knee portion has a tent-like shape and is designed to capture the hips and lower legs during radiation therapy procedures, while the foot portion is designed to hold the patient's feet. Both positioning pieces of the Knee-and-

Foot Lok can be used alone or in combination with each other. Both also interface with a lock-down bar, allowing the devices to be indexed to the radiation therapy couch.

The foam structure of these devices has a minimal attenuation factor, and blocks little of the radiation therapy beam. Foam support devices such as these have been widely used in radiation therapy patient positioning, and are available in many different shapes and sizes from different companies.

In practice, the Dual Leg Positioner and the Knee-and-Foot Lok devices are secured to the therapy couch tabletop by a lock-down mechanism, or by the patient's own weight. The patient is positioned supine on the treatment couch with his head and torso resting on a cushion or other immobilization device. The patient's thighs and lower legs are then draped over the knee support portion of the device, and the patient's feet are placed into the footrest depressions. This allows the patient's thighs, knees, calves, and feet to be comfortably supported in a manner that allows the patient to be positioned reproducibly for each treatment session. Radiation therapy is then administered in the usual fashion.

The Bionix Thigh Bolster and Foot Positioner is substantially equivalent to the Med-Tec Dual Leg Positioner and Knee-and-Foot Lok in design, form, and function. The Thigh Bolster and Foot Positioner consist of two parts, a thigh support and a footrest. The thigh support portion has a generally tent-like shape, with formed contours to support the thighs and calves. The thigh support portion is designed to interface with the Bionix Secure-Bar, allowing it to be secured to the radiation therapy treatment couch in an index-able fashion. The thigh support portion also has attachment points for interlocks that allow the use of low-melt thermoplastic during the patient immobilization procedure.

The Bionix Thigh Bolster and Foot Positioner is manufactured according to the FDA Good Manufacturing Practice guidelines using standard methods and practices. The Thigh Bolster and Foot Positioner is constructed using different materials than the Med-Tec Dual Leg Positioner and the Knee-and-Foot Lok. The Thigh Bolster and Foot Positioner are constructed of a thermoformed thermoplastic ABS shell with an air core that is an accepted standard in radiation therapy. The thermoformed ABS shell again provides stiffness and strength, while the air core allows for almost no attenuation of the radiation beam during the treatment process. The Thigh Bolster and Foot Positioner also have simple mechanical interlocks that allows the individual parts to be secured to the tabletop of the therapy couch. Other interlocks or clamps allow low-melt thermoplastic to be attached to the Thigh Bolster and Foot Positioner during the patient positioning process.

In clinical practice, the Thigh Bolster and Foot Positioner functions similarly to the Med-Tec Dual Leg Positioner and Knee-and-Foot Lok. The patient is generally positioned on the Thigh Bolster and Foot Positioner in the supine position, with his/her head and torso resting on a foam cushion for comfort. The patient's legs are draped over the Thigh Bolster and Foot Positioner, and the feet are placed into the Foot Positioner. Interlocks with the Bionix Secure-Bar allow both pieces to be indexed and securely attached to the radiation therapy couch. If desired, once the patient is correctly positioned, warm low-melt thermoplastic in its pliable state can be draped over the patient's knees and thighs where it conforms to the patient's anatomy. It is then secured to the Thigh Bolster and Foot Positioner using clamps or other simple mechanical interlocks. When it cools, the low-melt thermoplastic becomes rigid and retains the shape of the patient, allowing him to be positioned and re-positioned securely during the radiation therapy regimen.

Based on the almost identical design and similar features of the Bionix Thigh Bolster and Foot Positioner to the Dual Leg Positioner and Knee-and-Foot Lok currently manufactured and sold by Med-Tec, Inc., it is reasonable to expect that the two devices will have similar properties as regards to stiffness, support strength, and minimal attenuation of the radiotherapy beam, and should function in a substantially equivalent fashion during the patient positioning and the radiation therapy process. Both the Thigh Bolster and Foot Positioner and the Med-Tec Dual Leg Positioner and Knee-and-Foot Lok are intended for use in positioning and re-positioning patients during radiation therapy procedures, and both boards are employed in clinically identical fashions. Therefore, it is reasonable to conclude that the Thigh Bolster and Foot Positioner manufactured by Bionix Development Corporation is substantially equivalent in all aspects to the Dual Leg Positioner and Knee-and-Foot Lok manufactured by Med-Tec, Inc.

The Bionix Thigh Bolster and Foot Positioner is also similar in design and function to the Kneefix Cushion and the Feetfix Cushion, both legally marketed by SinMed BV as patient positioning devices and currently in use as accessories to radiation therapy systems. These devices have received the CE Mark, and conform to Class 1 medical devices under the CE regulations.

The Kneefix Cushion from SinMed BV is designed to position and immobilize the lower legs during supine hip and pelvic radiation therapy procedures. The Kneefix is consists of a coated, one-piece closed-cell foam support device with a tent-like shape. The wedge-shaped form and concave leg contours are designed to capture the hips and lower legs during radiation therapy procedures, improving the general positioning of the patient undergoing a course of external beam radiation therapy.

The SinMed Feetfix Cushion is a universal patient support cushion for radiation therapy and X-ray diagnostic procedures. It has a similar one-piece, closed-cell construction, and is designed to provide comfortable positioning of the feet with accurate and reproducible immobilization. The Feetfix Cushion is an aid to fast, easy and accurate positioning and immobilization of the legs for the treatment of the treatment of the prostate and pelvic region.

The foam structure of these devices has a minimal attenuation factor, and blocks little of the radiation therapy beam. Foam support devices such as these have been widely used in radiation therapy patient positioning, and are available in many different shapes and sizes from different companies.

In clinical practice, the Kneefix and Feetfix cushions are secured to the therapy couch by the patient's own weight. The patient is positioned supine on the treatment couch with his/her head and torso resting on a cushion or other immobilization device. The patient's thighs and lower legs are then draped over the Kneefix Cushion, and the patient's feet are placed into the depressions in the Feetfix Cushion. This allows the patient's thighs, knees, calves, and feet to be comfortably supported in a manner that allows the patient to be positioned reproducibly for each treatment session. Radiation therapy is then administered in the usual fashion.

Based on the almost identical design and similar features of the Bionix Thigh Bolster and Foot Positioner to the Kneefix and Feetfix cushions currently manufactured and sold by SinMed BV, it is reasonable to expect that the two devices will have similar properties as regards to

stiffness, support strength, and minimal attenuation of the radiotherapy beam, and should function in a substantially equivalent fashion during the patient positioning and the radiation therapy process. Both the Thigh Bolster and Foot Positioner and the SinMed Kneefix Cushion and Feetfix Cushion are intended for use in positioning and re-positioning patients during radiation therapy procedures, and both boards are employed in clinically identical fashions. Therefore, it is reasonable to conclude that the Thigh Bolster and Foot Positioner manufactured by Bionix Development Corporation is substantially equivalent in all aspects to the Kneefix Cushion and Feetfix Cushion manufactured by SinMed BV.

2. SuProne Plus

Date Prepared:	January 11, 2005
Submitter:	Bionix Development Corporation 5154 Enterprise Blvd. Toledo, Ohio 43612 419.727.8421 (phone) 419.727.4430 (fax)
Contact Person:	James Huttner M.D., Ph.D. [jhuttner@bionix.com (email)]
Trade Name:	SuProne Plus
Common Name:	Head and Neck Immobilization System
Classification Name:	Medical charged-particle radiation therapy system, accessory (per CFR section 892.5050).
Intended Use:	The SuProne Plus from Bionix Development Corporation is designed to be used for the positioning and re-positioning of patients for receiving radiation therapy.

Claim of Substantial Equivalence:

This product is similar in design and function to existing patient positioning devices currently in use as accessories to radiation therapy systems.

One such device is the Uni-frame Head and Neck Immobilization System, manufactured and sold by Med-Tec, Inc. of Orange City, Iowa. The Uni-frame Head and Neck Immobilization System is listed under regulation number 892.5050, and has been assigned the document control number K933227.

The Uni-frame Head and Neck Immobilization System from Med-Tec are designed to position and immobilize the head during radiation therapy procedures. The Uni-frame Head and Neck Immobilization System consist of a headboard that affixes to one of several types of base-plates. These base-plates may be flat or moveable to allow the patient's head and neck to be positively angled to different degrees of flexion, with the patient in the supine position.

Alternative base-plates allow the patient to be placed in the prone position, with his/her head resting on gel chin and forehead pads. The headboard features clamps or similar locking mechanisms to allow the concomitant use of low-melt thermoplastic for additional patient constraint.

The base-plates may be constructed of acrylic plastic, or may be composed of a carbon fiber/epoxy resin composite material. Likewise, the headboard used in conjunction with the base-plate may be constructed of acrylic plastic, or may be composed of a carbon fiber/epoxy resin composite material. Such materials are commonly used in the construction of immobilization devices for use in radiation therapy applications.

In clinical practice, the Uni-frame Head and Neck Immobilization System base-plates are secured to the therapy couch tabletop by a lock-down mechanism, or by the patient's own weight. A headboard is affixed to the selected base-plate. The patient is positioned in either the supine or prone position, depending on the therapy regimen selected by the radiation oncologist. The patient is positioned supine with his/her head resting on either a foam or thin plastic head rest for comfort, or on the gel chin and forehead pads for the prone position. Once positioned, a mask of low-melt thermoplastic may be used to further immobilize the patient. The low-melt thermoplastic mask is affixed to the headboard using the clamps or locking devices described earlier. Once properly positioned, the patient receives radiation therapy in the usual fashion.

The Bionix SuProne Plus is substantially equivalent to the Med-Tec Uni-frame Head and Neck Immobilization System in design, form, and function. The Bionix SuProne Plus is manufactured according to the FDA Good Manufacturing Practice guidelines using standard methods and practices. The SuProne Plus consists of a flat "headboard" comprised of a composite material with a carbon fiber/epoxy skin and a foam core that rests on a base-plate comprised of similar carbon fiber/epoxy composite material without the foam core. Such materials are commonly used in the manufacture of radiation therapy positioning devices because carbon fiber/epoxy composites have superior strength and rigidity, and show minimal attenuation of the radiation therapy beam.

The headboard is designed to hold a patient's head in either the supine or prone position during treatment. An open area in the center of the headboard allows for prone positioning of the patient; during treatment, the patient's forehead and cheekbones rests on a foam cushion for support and comfort. For supine positioning, the patient's head rests on a thin plastic headrest for comfort. With both prone and supine positioning, low-melt thermoplastic may be used to further constrain patient movement. The headboard has clamps or other locking mechanisms that allow the low-melt thermoplastic to attach firmly to the device.

The headboard rests on a base-plate made from a carbon fiber/epoxy resin composite material. This base-plate has three main elements: a base, side supports, and an upper frame that mates with the headboard. The base-plate base has simple mechanical interlocking systems that allow the device to be securely attached to the treatment couch tabletop using an attachment bar or similar device. This allows the SuProne Plus to be repeatedly located in the same position on the treatment couch tabletop for each therapy session.

The side supports of the base-plate provide rigidity and have semi-circular slots milled into them. The upper frame has a rigid, open box-like design, and has locating pins that mate with the underside of the headboard. The sides of the upper frame have threaded pins that mate

with the semi-circular slots in the side supports. These threaded pins allow the upper frame to move in an arcing fashion, following the semi-circular slots in the side supports. Tightening the threaded pins locks the upper frame at desired angle.

In clinical practice, the Bionix SuProne Plus functions similarly to the Med-Tec Uni-frame Head and Neck Immobilization System. The SuProne Plus is secured to the therapy couch tabletop either by a lock-down mechanism, or by the patient's own weight. The headboard is mated to the upper frame using the locating pins, and the upper frame is angled to the desired position, and then locked in that position by tightening the threaded pins. The SuProne Plus may be angled to provide either positive or negative neck flexion, as desired. The patient is placed in either the supine or prone position on the board with his head resting on a headrest or foam cushion over the open area. For enhanced patient constraint, a low-melt thermoplastic mask of the patient's head may be used. The mask is made by stretching warm low-melt thermoplastic over his/her head and allowing it to cool to rigidity, taking and holding the shape of the patient's head. The mask is then secured to the headboard using the clamps described earlier. In this fashion the patient is positioned reproducibly on the board. Radiation therapy is then administered in the usual fashion.

Based on the similarities in design, construction, features and function of the Bionix SuProne Plus to the Uni-frame Head and Neck Immobilization System currently manufactured and sold by Med-Tec Inc., it is reasonable to expect the two devices will have similar properties as regards to stiffness, support strength, and minimal attenuation of the radiotherapy beam, and should function in a substantially equivalent fashion during the patient positioning and the radiation therapy process. Both the SuProne Plus and the Med-Tec Uni-frame Head and Neck Immobilization System are intended for use in positioning and re-positioning patients during radiation therapy procedures, and both devices are employed in clinically identical fashions. Therefore, it is reasonable to conclude that the SuProne Plus manufactured by Bionix Development Corporation is substantially equivalent in all aspects to the Uni-frame Head and Neck Immobilization System manufactured by Med-Tec Inc.

The Bionix SuProne Plus is also similar in design and function to the Accufix Tilting Radiotranslucent Head holder legally marketed by WFR/Aquaplast Corp., of Wyckoff, NJ. The Accufix Tilting Radiotranslucent Head holder is listed under regulation number 892.5050, and has been assigned the document control number K021124.

The Accufix Tilting Radiotranslucent Head holder from WFR/Aquaplast is designed to position and immobilize the head during radiation therapy procedures. The Accufix Tilting Radiotranslucent Head holder consists of an angle-ating headboard affixed to a base-plate. The headboard is moveable to allow the patient's head and neck to be positively angled to different degrees of flexion, with the patient in the supine position. Alternatively, the patient may be placed in the prone position with his/her head supported in the open, central region of the headboard. The headboard features quick release swivel lock clamps to allow the concomitant use of low-melt thermoplastic for additional patient constraint.

The Accufix Tilting Radiotranslucent Head holder is composed of a carbon fiber/epoxy resin composite material. Such materials are commonly used in the construction of immobilization devices for use in radiation therapy applications. The carbon fiber/epoxy resin composite materials have been shown to have exceptional strength and rigidity, and have a minimal attenuation factor that blocks little of the radiation therapy beam.

In clinical practice, the Accufix Tilting Radiotranslucent Head holder base-plate is secured to the therapy couch tabletop by a lock-down mechanism, or by the patient's own weight. The patient is positioned in either the supine or prone position, depending on the therapy regimen selected by the radiation oncologist. In the supine position, the patient is positioned with his/her head resting on either a foam or thin plastic headrest for comfort. For prone positioning, optional attachments support the patient's head in the open, central region of the headboard. Once positioned, a mask of low-melt thermoplastic is be used to further immobilize the patient. Low-melt thermoplastic has the property of becoming soft and pliable when warm so that it can be stretched over and molded to the contoured shape of an object, in this case the patient. As it cools, it becomes rigid, and retains the object's shape. The low-melt thermoplastic mask is affixed to the headboard using the swivel clamps described earlier. Once properly positioned, the patient receives radiation therapy in the usual fashion.

Based on the similarities in design, construction, features and function of the Bionix SuProne Plus to the Accufix Tilting Radiotranslucent Head holder currently manufactured and sold by WFR/Aquaplast Corp., it is reasonable to expect the two devices will have similar properties as regards to stiffness, support strength, and minimal attenuation of the radiotherapy beam, and should function in a substantially equivalent fashion during the patient positioning and the radiation therapy process. Both the SuProne Plus and the WFR/Aquaplast Accufix Tilting Radiotranslucent Head holder are intended for use in positioning and re-positioning patients during radiation therapy procedures, and both devices are employed in clinically identical fashions. Therefore, it is reasonable to conclude that the SuProne Plus manufactured by Bionix Development Corporation is substantially equivalent in all aspects to the Accufix Tilting Radiotranslucent Head holder manufactured by WFR/Aquaplast Corp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2005

Bionix Development Corporation
% Mr. N. E. Devine Jr.
Responsible Third Party
Entela, Inc.
3033 Madison Ave., SE
GRAND RAPIDS MI 49548

Re: K050701
Trade/Device Name: Thigh and Foot Positioner, SuProne Plus
Regulation Number: 21 CFR 892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: IYE
Dated: March 18, 2005
Received: March 18, 2005

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use For:

- Thigh and Foot Positioner
- SuProne Plus

1. Thigh and Foot Positioner

Indications for Use

510(k) Number (if known): K050701

Device Name: Bionix Thigh and Foot Positioner

Indications for Use:

The Bionix Thigh and Foot Positioner patient positioning system developed and manufactured by Bionix Development Corp., Toledo, Ohio, is intended to be used for the positioning and re-positioning of patients undergoing or receiving a course of external beam radiation therapy for the treatment of cancer and other diseases.

It is intended to be used by or under the direction of a licensed physician.

Prescription Use _X_ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nancy C Brogdon
(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K050701